Remarks:

Claims 1, 2, 5–7, 9–11, 13, 14, and 17–21 were previously pending with claims 1, 18, and 20 being independent. Claims 1 and 11 are presently amended. Therefore, claims 1, 2, 5–7, 9–11, 13, 14, and 17–21 are currently pending with claims 1, 18, and 20 being independent.

In the Office Action dated September 12, 2006 ("OA"), claims 1, 2, 4–7, 9–11, 13, 14, and 17 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 4–6, 9, 11, 13, 14, and 18–21 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak, U.S. Patent Application Publication No. 2005/0187794, in view of Kraftson, U.S. Patent No. 6,151,581. Claims 2, 10, and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson and Oyama, U.S. Patent No. 5,496,175. Finally, claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson and admitted prior art.

The Application Invention

The application invention involves a novel method of enabling a patient to submit medical information directly to the patient's electronic medical record (EMR), wherein the EMR contains patient-specific, clinical information regarding the patient's health. The dictionary defines "clinical" as follows:

> of, relating to, or conducted in or as if in a clinic (as a medical clinic): as a: involving or depending on direct observation of the living patient <~diagnosis> <~examination> b: observable by clinical inspection <~tuberculosis> c: based on clinical observation <~picture> <~treatment>

WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 423 (2002).

Therefore, the electronic medical records that are acted upon by the claimed invention include information that is specific to a patient and that is obtained from direct observation

within a medical clinic. Thus, these electronic medical records are not just any records containing medical information, but are a particular class of medical records maintained by healthcare providers, such as doctors, and that include diagnoses and other notes and comments pertaining to a particular patient recorded by the doctor upon observation of the patient. In other words, the EMR is an electronic version of the patient's medical "file" that contains information personal to the patient and that is used by medical professionals to treat the patient.

As explained in the application, the submission of information to a patient's EMR is regulated by privacy laws such as HIPAA (which relates to the broad class of health information described as "individually identifiable health information" (http://www.hhs.gov/ocr/hipaa/)), which require healthcare providers to maintain the privacy of a patient's medical history and thus restrict access to the patient's medical records, including electronic medical records. Thus, healthcare providers are required to limit the manner in which a patient's personal information is added to an EMR database to ensure that only authorized personnel view the information stored in the database. For example, prior art methods of submitting a patient's medical information to an EMR involve a healthcare provider soliciting medical information from the patient and the provider manually recording the information into the EMR or recording the information on paper and giving the paper to a staff member who manually submits the patient's medical information to the EMR.

The application invention improves upon the prior art methods by enabling the patient to add personal medical information to his or her EMR with little or no assistance from a healthcare professional or staff member while preserving the privacy of the EMR database. Notably, the application invention accomplishes this without requiring a re-design of existing EMR database management software or software used by healthcare professionals to access patients' electronic medical records.

Particularly, the method of the application invention involves receiving a questionnaire from a patient, wherein the patient has filled out the questionnaire with the

patient's pertinent medical information including medical history, environment, and symptoms. The questionnaire is then scanned to convert the information on the questionnaire to computer-processable data. The computer-processable data is structured according to a Health Level Seven (HL7) medical data communications protocol and communicated to an EMR interface engine for addition to the patient's personal EMR in an EMR database. The HL7 protocol was developed to enable cross-platform communication of electronic medical record data between computer systems, such as a laboratory computer system and a physician's office computer system. According to the exemplary embodiment of the invention disclosed in the application, the data received from the patient is structured to simulate an HL7 laboratory record to render it compatible with an EMR interface engine. In other words, the interface engine treats the patient-submitted data as if it were received from a laboratory computer system. The application invention thus builds upon the HL7 protocol—which is already commonly used by physicians' computer systems—by enabling the computer systems to receive medical information directly from a patient and add the information to the patient's electronic medical record.

The patient submits the questionnaire prior to an appointment with the doctor, such as while the patient is in the waiting room on the day of the appointment. The information is scanned and added to the patient's personal EMR nearly instantaneously to enable the doctor to view the information as part of the patient's personal medical record at the appointment. Thus, the invention ultimately saves the doctor time by eliminating the need for the doctor to ask the patient questions about his or her health status, write the questions down, and ask a staff member to add the information to the patient's EMR.

Summary of U.S. Patent Application No. 2005/0187794 to Kimak

Kimak discloses a system for accessing or collecting electronic medical records stored on a variety of different private or public databases using a computer network, and merging and de-duplicating the records for presentation to an end-use care

provider. ¶¶ 3, 34. Specifically, the system of Kimak is used by point of service care providers to ascertain up-to-date immunization information for patients. ¶ 47. The system of Kimak uses the HL7 standard for communicating electronic medical record information, including immunization information, between remote servers and point of service care providers. *E.g.*, ¶¶ 5, 13, 34, 48, 51, and 57.

The system disclosed in Kimak does not receive information from patients, but rather manages electronic medical records which were created and maintained by care providers. ¶¶ 82, 119.

Summary of U.S. Patent No. 6,151,581 to Kraftson

Kraftson discloses a system and method for the "acquisition, management and processing of patient clinical information and patient satisfaction information received from a group of physician practices to provide practice performance information." (Kraftson, col. 2, lines 52–56). Kraftson uses the information gathered from multiple practices to create statistical summaries of practice results, including effectiveness of treatment, patients' perception of the quality of the healthcare, and costs. (*Id.*, col. 5, lines 23–37, 52–62).

Kraftson discloses using machine-readable survey forms to collect information from both doctors and patients, scanning the survey forms, converting the information on the forms to a pre-determined data format, and storing the data in a database for further processing. (*Id.*, col. 5, lines 1–13; col. 6, lines 1–8). The survey forms are completed by the patient and the physician "during a treatment session at [the] physician's practice" or after the treatment session. Importantly, the patient's portion of the survey relates exclusively to satisfaction with the physician's services. (*Id.*, col. 6, line 3; col. 11, lines 15–17; col. 12, lines 14–24; tables 1A, 1B; FIGs. 2A–2C). Furthermore, the patient's portion of the survey is completely anonymous, therefore information submitted by a patient cannot be associated with that patient. (*See id.*, FIGs. 2B, 2C (illustrating

patient surveys that include the declaration "THIS SURVEY IS TOTALLY ANONYMOUS")). Thus, Kraftson expressly discloses that the information collected by a patient is not associated with a particular patient, and therefore cannot be added to a patient specific electronic medical record.

The information submitted by the patient and the doctor is converted to "data records having a predetermined format." (*Id.*, col. 7, lines 8–9). Note that the information is converted to "data records," *not* medical records. The data records created by the system disclosed in Kraftson are entirely different than medical records. For example, the data records are created according to a format that facilitates statistical analysis of the information, such as storing prescription information in a sub-database separately from other elements of the information. (*Id.*, col. 7, lines 45–53). The data records are not used by a physician during a treatment session, and are never added to a patient's electronic medical record.

Thus, there are several notable differences between the method disclosed in Kraftson and the method of the application invention. First, the method of the application invention adds the information collected by the patient into the patient's patient-specific electronic medical record for use during a doctor's visit, while the method of Kraftson stores the satisfaction information collected from the patient in anonymous data records for statistical analysis after the doctor's visit. Second, the method of the application invention collects health status information from the patient while the method of Kraftson collects satisfaction information from the patient. Third, the method of the application invention receives information from the patient prior to a doctor's visit, while the method of Kraftson receives information from the patient during or after the doctor's visit. Finally, the method of Kraftson increases the amount of information the doctor must record during a visit with the patient, while the method of the application invention reduces the amount of information the doctor must record during a visit with the patient.

Additional information regarding the Kraftson reference is provided below where appropriate. A discussion of the other cited references is also provided below where

appropriate.

The rejections under 35 U.S.C. § 112

Turning now to the rejections based on 35 U.S.C. § 112, second paragraph, Applicant notes that claim 1 has been amended to change the language "machine readable questionnaire" to "machine readable card including a questionnaire." The new language is supported in the specification at paragraph 33, among other places. Claim 11, which depends from claim 1, has also been amended to reflect this change. Applicant believes that all claims presently conform to the requirements of § 112.

The rejection of claims 1, 18, and 20 under 35 U.S.C. § 103(a)

In the Office Action, claim 1 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Kimak in view of Kraftson. The Examiner asserted that at "the time of Applicant's invention, it would have been obvious to one of ordinary skill in the art to modify the method of Kimak with the teaching of Kraftson to use paper machine-readable questionnaires to obtain patient information." (OA, page 7). Applicant respectfully disagrees.

The Examiner must satisfy three criteria in order to establish the requisite *prima facie* case of obviousness: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine their teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or combination of references) must teach or suggest all the claim limitations. MPEP §706.02(j), *citing In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). Furthermore, "[t]he mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." *In re Fritch*, 23

USPQ2d 1780, 1783-84 (Fed. Cir. 1992); *see also In re Gordon*, 221 USPQ2d 1125, 1127 (Fed. Cir. 1984). Additionally, "if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." MPEP § 2143.01.

The Examiner has failed to establish the requisite *prima facie* case of obviousness because the Examiner has failed to identify a suggestion or motivation to combine Kimak with Kraftson, and further because the Examiner has failed to identify a reference or combination of references that teach or suggest each limitation of claim 1.

There is no suggestion or motivation to combine Kimak and Kraftson

There is no suggestion or motivation to combine Kimak with Kraftson as proposed by the Examiner. First, the system of Kraftson manages anonymous data records, while the system of Kimak manages patient-specific electronic medical records. As explained above in the sections titled "The Application Invention" and "Summary of U.S. Patent No. 6,151,581 to Kraftson," the data records managed by Kraftson are entirely different than the electronic medical records managed by Kimak. Electronic medical records, for example, are subject to laws and regulations such as HIPAA that govern their use and distribution. Kimak alludes to the restraints such laws and regulations place on the system, disclosing, for example, that point of service care providers must "enter the system through an approved method," and that providers can view data entered by other providers "provided proper disclosure forms have been obtained." (¶¶ 64, 76).

This is a significant distinction because the laws regulating the maintenance and use of electronic medical records are an obstacle to importing scan-card data into a patient-specific electronic medical record. Kimak discloses using the HL7 standard to communicate electronic medical record data between computer systems, and Kraftson discloses storing anonymous scan card data in anonymous data records, but the prior art does not contemplate using HL7 to communicate data from a card scanning machine to

a patient-specific electronic medical record. As explained in the Amendment dated June 20, 2006 (and supported by evidence submitted in an information disclosure statement accompanying the Amendment), for example, HL7 laboratory records are used for traditional laboratory tests, such as chemistry, hematology, and radiology, and—aside from Applicant's invention—are not used to import data from a scan-card machine into a patient's electronic medical record. Kraftson teaches that the records are anonymous so that "there is no danger of a patient's confidential information being inadvertently released," thus teaching away from the user of patient-specific data records. (Col. 12, lines 55–57). Kimak, in contrast, must use patient-specific electronic medical records, otherwise the records would be of no use to a physician viewing them. Because the system of Kimak is incompatible with the system of Kraftson, there is no suggestion or motivation to combine Kimak and Kraftson as proposed in the Office Action.

Second, even if the privacy laws and regulations associated with patient-specific electronic medical records could somehow be overcome to combine Kimak with Kraftson, the system of Kraftson never associates information collected from patients or physicians with particular patients or physicians, but rather collects and maintains the information anonymously. Therefore, it would have no use with Kimak because Kimak must be able to associate patient information with particular patients to be of any use. (*See, e.g.*, Kimak, ¶ 94, FIG. 8). Furthermore, the system of Kraftson teaches away from identifying patient or physician information with particular patients or physicians because Kraftson uses the information for statistical purposes. (Kraftson, col. 5, lines 23–38).

Third, the system of Kimak does not import information into a patient's electronic medical record, as recited in claim 1, but rather uses electronic medical records already created by physicians. It gleans information from the medical records to present to users, and even stores entire copies of medical records on physicians' computer systems, but does not import information into electronic medical records. Therefore, Kimak discloses no need to be able to import information from a patient to the patient's electronic medical record.

Fourth, the system of Kimak does not receive information directly from users, only from remote servers (¶ 66). Kimak is interested only in the treatment history—in this case immunizations—which is information obtained from physicians, not from patients. Because the system disclosed in Kimak is designed to be used only with treatment history data obtained from remote computer systems, there is no suggestion or motivation to modify Kimak as proposed in the Office Action to receive data directly from a patient via a machine-readable questionnaire.

Finally, neither Kraftson nor Kimak discloses how the information from the patient survey forms of Kraftson may be arranged "into a defined data structure simulating the protocol structure from a party having authorization to export data to the patient's" electronic medical record, as recited in claim 1.

For at least these reasons, there is no suggestion or motivation to combine Kimak and Kraftson as proposed in the Office Action.

Kimak and Kraftson do not teach or suggest each limitation of claim 1

The Office Action further fails to establish the requisite *prima facie* case of obviousness because it fails to identify a reference or combination of references that teach or suggest each limitation of claim 1. Even if Kimak is indiscriminately combined with Kraftson, for example, the combination does not teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

The system of Kimak includes "an electronic medical record *registry* system" (¶ 33, emphasis added), wherein the system accesses electronic medical records from "a plurality of medical service provider databases" and presents information from those records to users as a complete medical history of the patient. (¶¶ 74, 75; FIG. 3). While Kimak discloses "merging" medical records (¶ 12), this merging operation involves merging

information from multiple medical records into a single "view" or user interface element, and does not involve creating a new medical record. Kimak expressly discloses, for example, that "the merging does not result in creation of a storage location for a new record." (¶ 35). Moreover, when electronic medical records are communicated to the main registry database, the medical records are sent in their entirety and replaced by new, updated records when necessary. (¶¶ 77–81). Thus, information is never imported into a medical record, as recited in claim 1.

For at least this reason, Kimak does not teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1.

Kraftson also fails to teach or suggest "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health." The invention disclosed in Kraftson does not deal with electronic medical records that contain patient-specific, clinical information regarding the patient's health because, for example, the information gathered via the survey is stored in an anonymous database and used exclusively for statistical analyses based on patient satisfaction.

Column 6, lines 10–18 of Kraftson read:

> The System further includes a Data Analysis Processor 108 for analyzing the Physician/Patient/Management information according to selected data analysis packages such as Statistical Package for the Social Sciences (SPSS) or SAS, a Report Generation Module 110 for generating formatted reports containing results determined by the Data Analysis Processor 108, and an Outcomes Measurement Module 112 for recording and tracking performance of the System.

As can be seen, this section discloses analyzing information and generating a "formatted report," but fails to even suggest importing data into the patient's electronic medical record. As explained above, a patient's electronic medical record is not a report containing results

of an automated data analysis, but rather a private record containing that patient's personal, patient-specific, medical information that is viewable by a physician at the time the patient receives care from the physician.

Furthermore, Kraftson expressly teaches that the system disclosed therein generates two kinds of reports: 1) "a periodic report which summarizes general information about a quality level of the practice," and 2) "real time reports in response to physician queries" such as where a physician needs "information comparing the historical data concerning satisfaction of patient treatment in order for the physician to determine where a recently implemented change in treatment regimen improves or decreases patient satisfaction." (Kraftson, col. 8, lines 39–63). These reports are clearly not patient-specific electronic medical records viewable at the time of care, which is further evidenced by Kraftson's disclosure that physicians must "dial up" a report generation module, and receive "periodic practice reports" or "printed reports." (*Id.*, col. 5, lines 12–16).

It would not have been obvious to one of ordinary skill in the art to modify Kraftson to send "formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's electronic medical record contains patient-specific, clinical information regarding the patient's health." For example, adding information to a patient's medical record must be done in a manner that conforms with the privacy requirements described above, which, prior to Applicant's invention, was done manually with software accessible only by physicians and trained medical staff. Furthermore, Kraftson expressly teaches that the information collected from patients is anonymous satisfaction information, and that automated analyses of the information are shared among physician groups. These teachings are incompatible with the use of electronic medical records containing patient-specific, clinical information regarding the patient's health, which are subject to HIPAA and other privacy laws and regulations.

Therefore, for at least the reasons set forth above, neither Kimak nor Kraftson teaches or suggests "sending the formatted data to an assigned location for importing into the patient's patient-specific electronic medical record, wherein the patient's

electronic medical record contains patient-specific, clinical information regarding the patient's health," as recited in claim 1. Furthermore, Kimak and Kraftson considered in combination also fail to teach or suggest this element of claim 1. Kimak teaches using existing medical records to create a medical history of one or more patients, but does not teach or suggest importing data into a patients electronic medical record. Kraftson teaches away from using electronic medical records by teaching using other forms of records.

In the Office Action, claims 18 and 20 were rejected for reasons similar to those asserted in the rejection of claim 1. Therefore, the arguments set forth above addressing the rejection of independent claim 1 also apply to the rejection of claims 18 and 20.

Conclusion

For at least the reasons set forth above, applicant respectfully submits that claims 1, 2, 4–6, 9–11, 13–14, and 17–21 are now in allowable condition and requests a Notice of Allowance.

In the event of further questions, the Examiner is urged to call the undersigned. Any additional fee which is due in connection with this amendment should be applied against our Deposit Account No. 19-0522.

Respectfully submitted,
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